

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) <b>09 AUG 2005</b>	
Applicant's or agent's file reference  HRCM.P007WO	FOR FURTHER ACTION See paragraph 2 below
International application No.  PCT/IB04/52224	International filing date (day/month/year) 28 October 2004 (28.10.2004)
Priority date (day/month/year) 28 October 2003 (28.10.2003)	
International Patent Classification (IPC) or both national classification and IPC  IPC(7): G06C 3/00 and US Cl.: 235/88RC	
Applicant  CRAIG, H, RANDALL	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

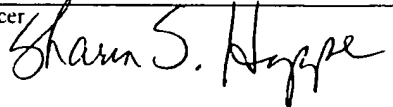
## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Karl D. Frech  Telephone No. 571-272-2390
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Form PCT/ISA/237 (cover sheet) (January 2004)

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IB04/52224

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language . . . , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/IB04/52224

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and explanations:**

Claims 1-31 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest in conjunction with all the other limitations of the subject claims:

Regarding claims 1-5, 7, 9 and 10: the sperm life plate rotating on the axis;

Regarding claims 6 and 8: the gestational ultrasound landmark probability curves;

Regarding claim 11: the third scale wherein the markers represent a percent calculation of likelihood of fetus survival upon delivery at a corresponding gestational age;

Regarding claim 12: the scale wherein the markers represent cervix length;

Regarding claim 13: the second scale wherein the markers represent a percent likelihood of ongoing pregnancy for an expecting mother under an age of forty years, and a third scale wherein the markers represent a percent likelihood of ongoing pregnancy for an expecting mother over an age of forty years;

Regarding claim 14: the first scale wherein the markers represent the percent likelihood of IVF pregnancy per cycle and a second scale wherein the markers represent a percent likelihood of COH-IUI pregnancy per cycle;

Regarding claim 15: the first scale wherein the markers represent a likelihood of Down's syndrome corresponding to a particular age of a mother, and a second scale wherein the markers represent likelihood of Aneuploid corresponding to a particular age of a mother;

Regarding claims 16-19: the evenly spaced dates spanning at least nine months and a second scale marked with landmarks of interest with respect to human gestation;

Regarding claims 20 and 21: the first plate having a scale bearing markings of height or weight disposed in a logarithmic spacing and second plate having a scale representing the other of height or weight of a patient, the first plate further having body mass index markings;

Regarding claims 22-29: the first plate having a scale bearing markings representing the biparietal diameter or the abdominal circumference and a second plate having a scale bearing markings representing the other of the biparietal diameter or the abdominal circumference; and

Regarding claims 30 and 31: the first plate having a scale indicative of a level of #-hCG.

Claims 1-31 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 300 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference HRCM.P007WO	<b>FOR FURTHER ACTION</b> <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/IB04/52224	International filing date ( <i>day/month/year</i> ) 28 October 2004 (28.10.2004)	(Earliest) Priority Date ( <i>day/month/year</i> ) 28 October 2003 (28.10.2003)
Applicant CRAIG, H, RANDALL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the Report**

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (See Box No. III)

4. With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1



as suggested by the applicant.



as selected by this Authority, because the applicant failed to suggest a figure.



as selected by this Authority, because this figure better characterizes the invention.

- b. ☐

none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB04/52224

### Box IV TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

#### NEW ABSTRACT

The gestational wheel calculator of the current invention greatly extends the function and usefulness of the basic gestational calculation wheel by providing increased accuracy of gestational dates by using an average cycle length adjuster, provides paternity information using a sperm exposure marker (420), provides more accurate ultrasound and other test measurements by using scales printed parallel to gestational age, and provide a means of accurately aligning these measurements with the proper calendar (430) or gestational date by including a transparent marker arm (600). In addition, normal range and error functions are included on the marker arm. A one-fourth year window is used to increase the surface area of information available for viewing charts, tables and promotions on the underlying base plate. Easier reading of the calculator is provided by special markers for the first day of each calendar month and by providing sub-marks for each day within a gestational week. Scheduling conflicts are improved by providing a weekday scale covering the entire nine-month duration of pregnancy. The other side of the gestational wheel can be used to provide additional promotional or informational items including rotating transparent windows to display additional surface area, to provide means of calculating algorithm solutions for body mass index, and display observational data for EFW, delta OD 450 and AFI.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB04/52224

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G06C 3/00

US CL : 235/88RC

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 235/88RC, 78R, 78RC, 85FC, 116; 40/111, 113, 114; 115, 595

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US 6,789,728 B1 (MUZZAMMEL) 14 September 2004 (14.09.2004), column 2, lines 32-61, fig. 2.	1-31
Y,P	US 6,637,137 B2 (COSTER et al) 28 October 2003 (28.10.2003), column 2, lines 10-65, fig. 1.	1-31
X,P	US 6,886,740 B1 (CRAIG) 03 May 2005 (03.05.2005), see entire document.	1-31
A	US 5,763,860 A (DENIS et al) 09 June 1998 (09.06.1998), see entire document.	1-31
A	US 4,092,521 A (WEISSHAAR) 30 May 1978 (30.05.1978), see entire document.	1-31

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

02 August 2005 (02.08.2005)

Date of mailing of the international search report

09 AUG 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Karl D. Frech

Telephone No. 571 272 2390

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB04/52224

Continuation of B. FIELDS SEARCHED Item 3:

BRS search terms: gestation?, sperm, calculat?, fertil?, disc, disk, wheel, ultrasound, cervix, survive, survival, menstrual, period, mother



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